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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|-------------------------|------------------|
| 10/016,858 | 12/14/2001 | . Karen Koch | 6225.200-US | 7430 |
| 7 | 590 07/30/2002. | | | |
| Reza Green, Esq. Novo Nordisk of North America, Inc. Suite 6400 | | | EXAMINER | |
| | | | HUI, SAN MING R | |
| | | | | |
| 405 Lexington Avenue New York, NY 10174-6401 | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |
| | | | DATE MAILED: 07/30/2002 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | 1 | Application No. | Applicant(s) | | | |
|---|--|--|--|--|--|--|
| ŧ | | 10/016,858 | KOCH ET AL. | | | |
| 2 20 | Office Action Summary | Examiner | Art Unit | | | |
| | - | San-ming Hui | 1617 | | | |
| | - The MAILING DATE of this communication app | | | | | |
| Period fo | | | • | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | D | | | | | |
| 1) | Responsive to communication(s) filed on | | | | | |
| 2a) | | s action is non-final. | | | | |
| 3)∐ | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 29-32 and 34-53 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) 29-32 and 34-53 are subject to restriction and/or election requirement. | | | | | | |
| Application | • | | | | | |
| | he specification is objected to by the Examiner. | | | | | |
| 10)∐ T | he drawing(s) filed on is/are: a)☐ accept | ed or b) \square objected to by the Exan | niner. | | | |
| — | Applicant may not request that any objection to the | | | | | |
| 11)∐ T | he proposed drawing correction filed on | | ed by the Examiner. | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| | he oath or declaration is objected to by the Exa | miner. | | | | |
| | nder 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a)[∑ | 〗All b)☐ Some * c)☐ None of: | | | | | |
| • | I. Certified copies of the priority documents | have been received. | | | | |
| 2 | 2. Certified copies of the priority documents | have been received in Applicatio | n No | | | |
| Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | | | |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 2) 🔲 Notice | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal Pa | PTO-413) Paper No(s) stent Application (PTO-152) | | | |
| S Patent and Trac | | | | | | |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 29-32 and 34, drawn to a tablet comprising 17β-estradiol, classified in class 424, subclass 464-483.
- II. Claims 35-53, drawn to a method of treating atropic vaginitis, classified in class 514, subclass 178.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as oral contraceptive.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming. Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui July 27, 2002

